

Claim Amendments

1-8. (Canceled)

9. (Withdrawn) A pharmaceutical composition [[,]] comprising [[a]] the mono-PEG-IL-10 [[of]] according to claim [[1]] 21 in combination with a pharmaceutically acceptable carrier.

10. (Withdrawn) A method of treating inflammation in an individual in need of such treatment, comprising administering to the individual a therapeutically effective amount of [[a]] the pharmaceutical composition [[of]] according to claim 9.

11. (Withdrawn) A process for preparing [[a]] the mono-PEG-IL-10 according to claim 21, comprising the step of:

reacting IL-10 with an activated PEG-aldehyde linker in the presence of a reducing agent to form the mono-PEG-IL-10 [[,]] under conditions in which wherein the linker is covalently attached to one amino acid residue of the IL-10.

12. (Withdrawn) The process [[of]] according to claim 11 wherein:

- (a) the reducing agent is sodium cyanoborohydride;
- (b) the activated PEG-aldehyde linker is PEG-propionaldehyde;
- (c) the PEG is a methoxy-PEG;
- (d) the linker is multi-armed;
- (e) the ratio of IL-10 to the sodium cyanoborohydride is from about 1:0.5 to 1:50;
- (f) the total molecular mass of all PEG comprising the PEG-aldehyde linker is from 3,000 daltons to 60,000 daltons; or
- (g) the reacting step is performed at a pH of 5.5 to 7.8.

13. (Withdrawn) The process [[of]] according to claim 11, wherein the ratio of IL-10 to the sodium cyanoborohydride is 1:5 to 1:15.

14. (Withdrawn) The process [[of]] according to claim 11, wherein the total molecular mass of all PEG comprising the PEG-aldehyde linker is from 10,000 daltons to 36,000 daltons.

15. (Withdrawn) The process [[of]] according to claim 11, wherein the reacting step is performed at a pH of 6.3 to 7.5.

16. (Withdrawn) The process [[of]] according to claim 14, further comprising a step selected from:

incubating the mono-PEG-IL-10 product in a buffer at pH 5.0 to 9.0;

[[and]] or

treating the mono-PEG-IL-10 product with 0.05 to 0.4 M hydroxylamine HCl salt.

17-20. (Canceled)

21. (New) A mono-pegylated Interleukin-10 (mono-PEG-IL-10) comprising one or more polyethylene glycol (PEG) molecules covalently attached via a linker to a single amino acid residue of IL-10, wherein said amino acid residue is the alpha amino group of the N-terminal amino acid residue or the epsilon amino group of a lysine residue.

22. (New) The mono-PEG-IL-10 of claim 21, wherein one or two PEG molecules are attached to said single amino acid residue.

23. (New) The mono-PEG-IL-10 of claim 21, wherein one subunit of said IL-10 has the formula:

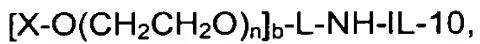


wherein b is 1-9 and L is a C<sub>2-12</sub> alkyl linker moiety covalently attached to a nitrogen (N) of said single amino-acid-residue.

4 24. (New) The mono-PEG-IL-10 of claim 23, wherein b is 1 and L is -CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>-.

5 25. (New) The mono-PEG-IL-10 of claim 21, wherein PEG is covalently attached to the nitrogen of the alpha amino group of the N-terminal amino acid residue.

6 26. (New) The mono-PEG-IL-10 of claim 21, wherein said IL-10 has the formula:



7 wherein X is H or C<sub>1-4</sub> alkyl, n is 20 to 2300, b is 1 to 9 and L is a C<sub>1-11</sub> alkyl linker moiety which is covalently attached to the nitrogen (N) of the alpha amino group at the amino terminus of one IL-10 subunit; provided that when b is greater than 1, the total of n does not exceed 2300.

8 27. (New) The mono-PEG-IL-10 of claim 26, wherein L is -CH<sub>2</sub>CH<sub>2</sub>CH<sub>2</sub>-.

9 28. (New) The mono-PEG-IL-10 according to claim 21, wherein said mono-PEG-IL-10 has greater than 30% of the activity of unconjugated IL-10.

10 29. (New) A composition of pegylated IL-10 comprising the mono-PEG-IL-10 according to claim 21, wherein the population of mono-PEG-IL-10 is at least 80% of a positional isomer in which the PEG is conjugated to the N-terminal amino acid of one subunit of IL-10.

11 30. (New) A process for preparing a pharmaceutical composition comprising the mono-PEG-IL-10 according to claim 21, comprising mixing the mono-PEG-IL-10 with a pharmaceutically acceptable carrier.